



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/068,253	06/09/98	SHIMURA T	146.1286 <sup>mk</sup>

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HM12/0302

EXAMINER	
MOEZIE, F	
ART UNIT	PAPER NUMBER
1654	6

DATE MAILED: 03/02/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/068,253

Applicant(s)  
SHIMURA et al

Examiner  
Fatemeh Moezie

Group Art Unit  
1654



☒ Responsive to communication(s) filed on 04/24/98 05/13/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-11 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

If applicant desires priority under 35 U.S.C. 371 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Preliminary amendment filed 13 May 1998 have been entered. Claims 4-5 have been amended and claims 8-11 have been added. Hence, claims 1-11 are pending in this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "material" and "agent" render the claims indefinite as to the claims metes and bounds. Substitution of terms such as; --aqueous solution-- or any other accepted term that can be supported by the specification, is suggested.

In claims 3 and 9 the term "aqueous solution" do not find antecedent bases in claims 1 and 7, respectively.

Claims 1 and 6 are duplicative of one another, being drawn to the same formulation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over RON, E., et al., WO 93/00050, as applied to claim 1-11 above, and further in view of the conventional knowledge set forth in The Condensed Chemical Dictionary, pages 240, 296, 718, 891, 991.

The primary reference teaches pharmaceutical formulations of osteogenic proteins comprising an osteogenic protein-sequestering material, abstract. The sequestering material useful are "poly(ethylene glycol), polyoxyethylene oxide" page 8, lines 17-26.

However, the primary reference does not teach the use of polyoxyethylene-polyoxypropylene glycol in the formulations.

The Dictionary discloses that "Pluronic" are non-ionic <sup>sequestering</sup> compounds which can be used as binders, stabilizers, dispersing agents, etc. in a composition, pp 825 and 991. Further, see the Dictionary entry for sequestration compounds and coordination compounds on pp 240,296.

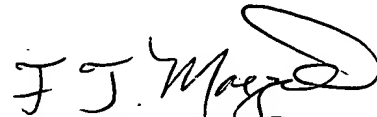
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It would have been prima-facie obvious to one of ordinary skilled in the art at the time the invention was made to use the "pluronic" for its sequestering properties as set forth in the primary reference and expect to obtain an osteogenic protein formulation for use as claimed.

The references cited on Form 1449 could not be considered. If applicant wishes to make them of record, applicant would have to submit either an English language translation(s) thereof or cite and provide their equivalent English language document(s).

Any inquiry concerning this communication should be directed to Examiner Moezie at telephone number (703) 305-4508.

  
F. T. MOEZIE, PH.D.  
PRIMARY EXAMINER  
ART UNIT 1654